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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,235	03/17/2004	Elizabeth Dzeng	Stanford S03-060	5638
39843	7590	12/08/2009	EXAMINER	
BELL & ASSOCIATES 58 West Portal Avenue No. 121 SAN FRANCISCO, CA 94127			GIBSON, ROY DEAN	
			ART UNIT	PAPER NUMBER
			3739	
			NOTIFICATION DATE	DELIVERY MODE
			12/08/2009	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/803,235	<b>Applicant(s)</b> DZENG ET AL.	
	<b>Examiner</b> Roy D. Gibson	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13, 14, 37-42 and 45-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13, 14, 37-42 and 45-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### ***Entry of Amendment***

Applicant's amendment filed on August 28, 2009 is acknowledged. Claims 13, 14 and 34-50 are currently pending.

### ***Prior Rejections or Objections***

The following comments pertain to the rejections or objections in the most recent Office action mailed on January 14, 2009. Rejections under 35 U.S.C. 112 and 103 are withdrawn, however, new grounds of rejection and/or objection are presented below.

### ***Claim Objections***

The claims are objected to because they include reference characters which are not enclosed within parentheses. Reference characters corresponding to elements recited in the detailed description of the drawings and used in conjunction with the recitation of the same element or group of elements in the claims should be enclosed within parentheses or deleted so as to avoid confusion with other numbers or characters which may appear in the claims. See MPEP § 608.01(m).

### ***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: the groove of claim 1 is not shown in Figure 10 nor does the Specification recite an element no. for this groove. Corrected Specification and drawing sheets in

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compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13, 14, 37-42 and 45-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noda et al. (6,726,653) in view of Knowlton (6,427,089).

Noda et al. discloses a heat exchange catheter system for cooling a target organ, the heat exchange catheter system adapted for placement within an anatomical structure of a subject, comprising: (a) a first elongate tubular body having a proximal end and a distal end, (b) a second elongate tubular body having a proximal end and a distal end, (c) a balloon defining a lumen in fluid communication with both the first elongate tubular body and the second elongate tubular body so as to form a continuous

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fluid pathway, further comprising a third elongate tubular body having a proximal end and a distal end, the third elongate tubular body disposed longitudinally within the second elongate tubular body, and wherein the balloon is sealably affixed to the outer surface of the first elongate tubular body and sealably affixed to the outer surface of the third elongate tubular body (see Figures 8 and 9 with the guidewire (174) with lumen of Figure 10B added) the lumen further comprising a thermal exchange composition, wherein the thermal exchange composition is disposed within the continuous fluid pathway formed by the second elongate tubular body, the first elongate tubular body, and the balloon lumen and wherein the thermal exchange composition is selected from the group consisting of a solid, a gel, a liquid, and a gas, and wherein the balloon, when inflated has a longitudinally disposed groove (Figure 8 regions between the cavities 107 and 110) upon its outer surface and is adapted to conform in shape and size to the interior of the anatomical structure such that when placed within the anatomical structure and inflated, the outer surface of the balloon is at least partially in contact with the inner surface of the anatomical structure providing a heat exchange surface by which heat is exchanged between the anatomical structure and interior of the balloon, and whereby the target organ adjacent to the anatomical structure is thereby cooled (col. 5, lines 30-67, col. 7, lines 56-65 and col. 8, line 49-col. 9, line 23).

But, Noda et al. fail to specifically disclose, (d) a transducer (claim 13 limitation) or further comprising an ultrasound transducer (claim 42 limitation) affixed to the catheter. But, Knowlton discloses a stomach treatment apparatus with an ultrasound transducer used to image the device distal end (col. 13, lines 21-26). Therefore, at the

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time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of Noda et al., as taught by Knowlton, to provide a means to image and therefore, locate and position the treatment apparatus as required by the procedure.

Further to claims 34-36, Noda et al. disclose the method essentially as claimed, wherein the cooling rates could obviously be determined by a skillful artisan without undue experimentation.

Further to claims 37-40, Noda et al. disclose wherein the second elongate tubular body is disposed longitudinally within the first elongate tubular body;

wherein the subject is a human subject;

wherein the anatomical structure can be the esophagus, and the target organ can the heart;

wherein the balloon is shaped and sized for placement in the anatomical structure selected from the group consisting of: the esophagus, the oral cavity, the nasopharyngeal cavity, the auditory tube and tympanic cavity, the sinus of the brain, the arterial system, the venous system, the larynx, the trachea, the bronchus, the stomach, the duodenum, the ileum, the colon, the rectum, the bladder, the ureter, the ejaculatory duct, the vas deferens, the urethra, the uterine cavity, the vaginal canal, and the cervical canal; and

wherein the target organ is selected from the group consisting of: the myocardium of the heart, the lungs, the thymus, the thyroid, the liver, the pancreas, the kidney, the uterus, the ovary, the testis, the prostate, and the brain.

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Further to claims 41 and 45-50 the claim limitations are directed to an intended use of the device rather than to a structural modification and the Noda et al. device would obviously be capable of providing the claimed cooling rates (col. 10, line 51- col.11, line 21).

Further to claim 43, the examiner maintains that it would have been obvious to one of ordinary skill in the art to provide a guiding catheter or sheath over at least a portion of the first elongate tubular body to assist in positioning the catheter within the patient's body, as is well known in the art.

Further to claim 44, the examiner maintains that it would have been obvious to a skillful artisan to provide a pill (digestive composition) at the end of the guide wire to assist the patient in swallowing the guidewire at the beginning of the method or procedure.

### ***Response to Arguments***

Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection. In the independent claims if the depth of the groove on the surface of the balloon were limited in depth so as not to be in contact with the first elongate tubular structure, then these claims would be allowable over the references cited herein.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on Tu-Th, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Roy D. Gibson/  
Primary Examiner  
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December 3, 2009